657—13.29(126,155A) Environmental monitoring requirements.

13.29(1) *Certification required.* All cleanrooms, laminar airflow workbenches, and barrier isolators shall be certified by an independent contractor according to ISO Standards 14644-1:1999(E) and ISO Standards 14664-3:2005(E), or National Sanitation Foundation Standard 49, for operational efficiency at least every six months and whenever the device or room is relocated or altered or whenever major service to the facility is performed. Inspection and certification records shall be maintained for two years from the date of certification.

13.29(2) *Procedures required.* The pharmacy shall establish written procedures appropriate for the risk level preparations compounded by the pharmacy. The procedures shall include environmental testing, end testing, and evaluation of validation results.

a. Air sampling. Microbial sampling of air within the primary engineering control devices, buffer areas, and anterooms is required at least semiannually as part of the recertification of facilities and equipment. If compounding occurs in multiple locations within an institution, environmental sampling is required for each individual compounding area.

b. Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the anteroom and between the anteroom and the general pharmacy area. The gauge/meter shall alert the pharmacy when air conditions do not meet recommended conditions, and all compounding shall be discontinued until the alarm condition is corrected. If the gauge/meter is incapable of alerting the pharmacy to inappropriate conditions, the pharmacy shall monitor and review the gauge/meter daily and document the results in a log.